CANCER GENETICS®

Empowering Personalized Cancer Treatment

DLBCL Complete℠

Diffuse Large B-Cell Lymphoma

DLBCL | COMPLETE℠

DLBCL Complete℠ is a unique suite of common and proprietary tests including biomarkers with diagnostic and prognostic value. CGI's Complete℠ programs are intended to assist in devising the best course of treatment to improve patient outcomes.

For more information, please visit www.cancergenetics.com

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Diffuse large B-cell lymphoma (DLBCL) is a clinically, pathologically and genetically heterogeneous disease. An estimated 190,000 people in the United States suffer from DLBCL, and over 25,000 new U.S. cases are diagnosed each year, accounting for ~40% of all Non-Hodgkin's Lymphoma (NHL) cases. DLBCL is an aggressive lymphoma with immunochemotherapy as the standard care. While DLBCL is considered an immunochemo-sensitive disease, only about 60% of patients are cured. Therefore, risk stratification is highly desirable for patients with DLBCL in order to differentiate those who are likely to have refractory disease or relapse from those who may be cured with the standard therapy.

DLBCL Complete℠ integrates the latest diagnostic and prognostic molecular markers including proprietary testing to risk-stratify individual patients for disease progression, response to treatment, and overall prognosis.

DLBCL Complete℠ Work-Up

New Diagnosis

Diagnostic & Prognostic Assessment

- Morphology
- Immunophenotyping **(Flow, IHC)**
- B-Cell Clonality **(Molecular Dx)**
- FISH - NHL Panel **(Cytogenetics)**
- Karyotyping **(Cytogenetics)**

Prognostic & Theranostic Assessment

- Proliferation Index by Ki-67 **(IHC)**
- MYC Expression **(IHC)**
- GCB/Non-GCB Subtyping **(IHC)**
- *TP53* Mutation Analysis **(Molecular Dx)**
- MatBA®-DLBCL **(Molecular Dx)**

Monitoring, Disease Progression & Recurrence

Prognostic & Theranostic Assessment

- *TP53* Mutation Analysis **(Molecular Dx)**
- MatBA®-DLBCL **(Molecular Dx)**
- MYC, Ki-67 **(IHC)**
- Karyotyping **(Cytogenetics)**

DLBCL Complete℠ Test Offering

Physicians can order tests individually or allow CGI directors to determine a panel evaluation as determined necessary.

Morphology, IHC, ISH

Morphology

Morphological and histologic subtype assessments provide diagnostic information for the lymphoma.

B-Cell Lymphoma Panel - IHC

This panel provides diagnostic information on the immunophenotype of the lymphoma. The antibodies included in this panel are CD3, CD5, CD10, CD20, PAX5, CD21, CD43, Bcl-2, Bcl-6, CyclinD1, EBER, Ki-67 and Mum-1.

GCB vs. Non-GCB Subtyping

Cell-of-origin subtypes are determined by IHC based on the protein expression profiling of CD10, BCL6 and MUM1. Additional antibodies employed for subtyping of difficult cases includes GCET-1, LMO-2 and FOXP-1. Patients with the GCB subtype have a more favorable outcome compared to non-GCB.

cMYC, Ki-67

Expression levels of cMYC protein and Ki-67 are determined by IHC. High MYC expression levels in concert with high BCL2 low BCL6 expression are associated with poor response to the standard R-CHOP therapy and may respond better to a more intensive chemotherapy regimen. Ki-67 expression levels provide prognostic value in predicting proliferation rate.

Flow

Lymphoid Panel

The lymphoid panel determines expression levels of cell surface antigens by flow cytometry that provide diagnostic information for DLBCL. This panel includes CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11c, CD19, CD20, CD23, CD38, CD45, CD56, CD57, Kappa, Lambda.

Molecular Diagnostics

MatBA®-DLBCL Array-CGH (CLIA and New York State approved)

The Mature B-Cell Neoplasm Array for DLBCL (MatBA®-DLBCL) assists in patient stratification for risk-adapted therapy when performed at diagnosis. MatBA®-DLBCL assesses the presence of individual prognostic markers as well as genome complexity as measures of overall survival following front-line immunochemotherapy.

TP53 Mutation Analysis

The presence of a *TP53* mutation is associated with shorter survival and resistance to chemotherapy.

B-Cell Clonality

This assay utilizes PCR to detect a clonal *IGH* rearrangement in isolated DNA. Detection of clonality is an important tool in the diagnosis of B-cell neoplasms.

Cytogenetics

FISH - NHL Panel

The FISH analysis provides high sensitivity information about key genomic diagnostic alterations and prognostic markers, including 3q27 [*BCL6*-Break Apart], t(14;18) [*IGH/BCL2*], t(8;14) [*MYC/IGH*], t(11;14) [*CCND1/IGH*], 18q21 [*MALT1*-Break Apart], and 8q24 [*MYC*-Break Apart].

Karyotyping

Karyotyping enables genome-wide detection of aberrations at low resolution that have a diagnostic and prognostic significance.

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Specimen Requirements

	Test	Turn Around Time (Mon. - Sat.)	Bone Marrow	Tissue
Morphology, IHC, ISH	**Morphology**	2-4 days	Bone marrow core	FFPE tissue block* at room temp **or** 0.5 cm^3 fresh tissue in RPMI on ice
	B-Cell Lymphoma Panel	2-4 days		
	GCB/Non-GCB Subtyping	2-4 days		
	MYC, Ki-67	2-4 days		
Flow	**Lymphoid Panel**	1-2 days	1 **Green**/NaHeparin **or** 1 **Lavender**/EDTA tube (2 ml) at room temp.	0.5 cm^3 fresh tissue in RPMI on ice
Molecular Dx	**MatBA®-DLBCL**	10-14 days	1 **Lavender**/EDTA tube (2-3 ml) at 4°C	FFPE tissue block* (>70% tumor) at room temp. **or** 0.2 cm^3 fresh tissue (>50% tumor) in RPMI on ice
	***TP53* Mutation**	7-10 days		
	B-Cell Clonality	7-10 days		
Cyto.	**FISH Panel**	3-5 BM; 5-7 Tissue	1 **Green**/NaHeparin tube (3-5 ml) at room temp.	FFPE tissue block* at room temp **or** 0.5 cm^3 fresh tissue in RPMI on ice
	Karyotype	5-7 days		
DLBCL Complete℠ Panel		10-14 days	1 **Green**/NaHeparin **or** 1 **Lavender**/EDTA tube (5-7 ml) at room temp.	FFPE tissue block* at room temp. **or** 0.5 cm^3 fresh tissue in RPMI on ice

* If FFPE tissue block is not available, fifteen 3-5 µm unstained slides are also acceptable.

CGI Laboratory Licensure

CAP (Laboratory #: 7191582, AU-ID: 1434060), CLIA (Certificate #: 31D1038733), New Jersey (CLIS ID #: 0002299), New York State (PFI: 8192), Pennsylvania (031978), Florida (800018142), Maryland (1395).

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